DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 2, 2016

Sirona Dental Systems GmbH
Mr. Kofi Aninakwa
Legal Services Engineer
Sirona Dental Systems, Inc.
30-30 47th Avenue, Suite 500
Long Island City, New York 11101

Re: K160099
Trade/Device Name: CEREC SpeedGlaze
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: Class II
Product Code: EIH
Dated: April 13, 2016
Received: April 27, 2016

Dear Mr. Aninakwa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160099

Device Name
CEREC SpeedGlaze

Indications for Use *(Describe)*
Glazing of individually designed dental restorations from dental ceramics.

The CEREC SpeedGlaze Spray is used for coating dental restorations made from Sirona CAD/CAM materials. It is administered extra-orally and is indicated for crowns, inlays, onlays, partial crowns and bridges in the anterior and posterior tooth region.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

for

Sirona Dental Systems
CEREC SpeedGlaze
K160099

1 SPONSOR

Sirona Dental Systems GmbH
Fabrikstrasse 31
64625 Bensheim
Germany
Contact Person: Kofi Aninakwa
Telephone: 718-482-2248

2 DATE PREPARED : 5-25-2016

3 DEVICE NAME

Proprietary Name	: CEREC SpeedGlaze
Common/Usual Name	: Powder, Porcelain
Classification Name	: Porcelain powder for clinical use
Regulation Number	: 21 CFR 872.6660
Product Code Device	: E I H
Class	: 2

4 PREDICATE DEVICES

Device Name: NOVA CERAMIC SPRAY GLAZE AND TRU-PAQUE, OPAQUE PORCELAIN
K Number: K030859
Manufacturer : ENAMELITE LLC

5 INDICATIONS FOR USE

Glazing of individually designed dental restorations from dental ceramics.

The CEREC SpeedGlaze Spray is used for coating dental restorations made from Sirona CAD/CAM materials. It is administered extra-orally and is indicated for crowns, inlays, onlays, partial crowns and bridges in the anterior and posterior tooth region.

6 DEVICE DESCRIPTION AND FUNCTION

The CEREC SpeedGlaze Spray is used to glaze dental restorations made from the Sirona CAD/CAM materials CEREC Zirconia, inCoris TZI C, CEREC Blocs C, CEREC Blocs C PC and CEREC Blocs C In. The spray meets the requirements of the ISO 6872:2008 "Dentistry - Ceramic materials". The product consists of a coated aluminum can cap, filled with a glaze and a valve and a spray nozzle, for applying the glaze.
The CEREC Speed Glaze Spray is suitable for the coating of dental restorations from the Sirona CAD/CAM materials: CEREC Zirconia, inCoris TZI C, CEREC Blocs C, CEREC Blocs C PC and CEREC Blocs C In. The CEREC SpeedGlaze spray has to be administered extraorally.

It is indicated for the following parts of dentistry:

- crowns, inlays, onlays, partial crowns and bridges in the anterior and posterior tooth region.

The product has 8 components as shown below:

Table 1 : Physical Components

Component	Remark / Description
1. Can:	Aluminum monobloc spray can
2. Valve:	For releasing the contents when engaged
3. Can cap	PP - Polypropylene, Plastic
4. Spray nozzle:	For spraying onto restoration
5. 14mm Glass balls	For mixing of the components before spraying
6. Glaze Ceramic	Silicate glass
7. Instruction for use	Instructions for use document
8. Folding carton	Package

The properties including the firing temperature, particle size and solubility are shown below. The components of the CEREC SpeedGlaze can also be found in the subsequent table.

Property	Value
Coefficient of thermal expansion	$7.5 \times 10^{-6} \times K^{-1} \pm 0.5 \cdot 10^{-6} K^{-1}$
Transformation temperature	490° C ± 10°C
Bending strength	> 50 MPa
Chemical solubility	< 100 µg x cm^{-2}
Granulometry/particle size	D50 = 6µm ± 0.6µm
Cytotoxicity	no cytotoxicity
Radioactivity	< 1 Bq x g^{-1} U^{238}

7 PRINCIPLES OF OPERATION

The underlying scientific concept is that the glaze is applied by spray jet on to the surface of the ceramic restorations and a firing process is carried out in the chairside oven CEREC SpeedFire. Commercially available chairside ovens like the Vita Vacumat and Ivoclar Programat can also be used.

The product is composed of a can which is coated with epoxyphenol and a spray mechanism including a valve, nozzle and can cap. These allow for the extraoral spraying of the glaze onto the restoration.

The CEREC SpeedGlaze consists mainly of a glaze ceramic, organic excipients and propellant gas. When the valve assembly is engaged, the composition from the container is released and sprayed onto the restoration. During finring, the organic excipients burn without leaving any residue.

The glaze meets the requirements of the ISO 6872:2008 "Dentistry - Ceramic materials".

8 TECHNOLOGICAL CHARACTERISTICS SUMMARY

Comparison to Predicate Device

The CEREC SpeedGlaze is similar to the Nova Ceramic Spray Glaze by Enamelite LLC. The CEREC SpeedGlaze is intended for coating dental restorations. It is made of silicate glass and is applied to dental restorations in an aerosolized form. Similarly, the Nova Ceramic Spray Glaze is intended for glazing dental restorations and is made of glass frit with similar compositions as the CEREC glaze material. It has the same classification name (Porcelain Powder for clinical use) and product code (EIH) as the CEREC SpeedGlaze. Both devices consist of refined aerosol delivery systems used to apply the glaze. They have the same working principle in that the glaze is applied by a spray jet onto the restoration and a firing process is carried out to melt the glaze.
The CEREC SpeedGlaze has similar composition to the Nova Ceramic Spray Glaze.
Both sprays use non-CFC propellants to eject the contents. Similar wetting agents are also used in both sprays.

Both sprays require firing of the restoration after application of the glaze.
The main difference between the CEREC SpeedGlaze and the Nova Ceramic Spray Glaze is the differences in organic excipients (solvents and pigments). However this is not significant as the excipients burn without residue upon firing.
Furthermore properties such as bending strength, coefficient of thermal expansion, cytotoxicity, and chemical solubility were tested according to ISO standards ISO 6872 and ISO 7405, and meet the requirements.

	Nova Ceramic Spray Glaze (K030859)	CEREC SpeedGlaze (Subject Device, K160099)	Discussion
Indications For Use	The Enamelite Porcelains Powders are aerosol devices intended to be used as spray applications of ceramic porcelains and glazes for dental restorations (crowns and bridges), which are produced in dental laboratories.	Glazing of individually designed dental restorations from dental ceramics. The CEREC SpeedGlaze Spray is used for coating dental restorations made from Sirona CAD/CAM materials. It is administered extra-orally and is indicated for crowns, inlays, onlays, partial crowns	Both devices have similar indications for use. The Nova Ceramic spray glaze is indicated to be used with a wider array of crowns and bridges while the CEREC SpeedSpray is indicated to be used with only

		and bridges in the anterior and posterior tooth region.	Sirona materials since only these materials have been tested.
Device Name	Nova Ceramic Spray Glaze	CEREC SpeedGlaze	NA
Sponsor	ENAMELITE LLC	Sirona Dental Systems GmbH	NA
CFR Section	21 CFR 872.6660	21 CFR 872.6660	Same
Product Code	EIH	EIH	Same
Type and Class according to ISO 6872	NA	Type 1, Class 1A	While the type and class of Nova Ceramic Spray Glaze is unknown, the chemical and physical properties are similar
Main Chemical Compositions	-Non-CFC propellant (such as isobutane, butane or mixtures) -Glass frit	- Isobutane - Silicate Glass	While the exact percentages of the predicate are unknown, the main composition of both sprays are similar. The Glaze powder, propulsion gas and wetting agents are similar. Differences in organic excipients (solvents, pigments) are not

			relevant as they burn without residue
Physical Properties	Physical state of glass: Powder - CTE of ~10.1 x 10^{-6} x K^{-1} (Enamelite AEROpaque)	Physical state of glass: Powder - CTE of 7.5 x 10^{-6} x K^{-1} ± 0.5 ·10^{-6} K^{-1}	Both devices have similar physical properties and both glazes are in powder form.
Technology and Main Working Principle	The glaze is applied by spray jet on to the surface of the restorations and a firing process is carried out	The glaze is applied by spray jet on to the surface of the restorations and a firing process is carried out	Same
Performance Standards	ISO 6872 Dentistry - Ceramic materials	ISO 6872 Dentistry - Ceramic materials	Same
Storage	Avoid exposure to temperatures exceeding 50 °C/122 °F.	Avoid exposure to temperatures exceeding 50 °C/122 °F.	Same

9 PERFORMANCE DATA

Non clinical tests have been performed for CEREC SpeedGlaze to investigate the physical, chemical and biological properties. The CEREC SpeedGlaze consists of a glaze ceramic, propellant gas, pigments and other components and meets the requirements of International Standard ISO 6872 - Dentistry - Ceramic Materials. A critical assessment based on clinical data research along with a risk-benefit-ratio assessing the usability of the intended use was provided to the FDA. Performance Tests were performed to measure the CEREC SpeedGlaze Properties below:

Property	Protocol	Result
Physical state	Visual inspection	passed
Granulometry	Laser particle sizer	passed
Appearance (color, transparency)	Visual inspection	passed

Firing Temperature	Internal protocol	Passed
Coefficient thermal expansion	ISO EN DIN 6872	passed
Transformation temperature	ISO EN DIN 6872	passed
Bending strength	ISO EN DIN 6872	passed
Chemical solubility	ISO EN DIN 6872	passed
Radioactivity	ISO EN DIN 6872	passed
Cytotoxicity	ISO EN DIN 10993-5	passed
Thermal Shock Test of Glaze	Internal protocol	passed
Chemical Analysis	DIN 15169	passed

The CEREC SpeedGlaze also follows the Standards below:

Performance Standards Applied
ISO 10993-1:2009 Biological Evaluation Of Medical Devices -- Part 1: Evaluation And Testing Within A Risk Management Process
ISO 6872 Third Edition Dentistry - Ceramic Materials
ISO 14971 Medical Devices - Application Of Risk Management To Medical Devices
ISO 15223-1 Second Edition 2012-07-01 Medical Devices - Symbols To Be Used With Medical Device Labels, Labeling, And Information To Be Supplied - Part 1: General Requirements
IEC 62366-1 Medical devices - Application of usability engineering to medical devices
ISO 7405 Second Edition 2008-12-15 Dentistry - Evaluation Of Biocompatibility Of Medical Devices Used In Dentistry [Including: Amendment 1 (2013)]
DIN EN 60721-3-2 Classification of environmental conditions - Part 3: Classification of environmental parameters and their severities; Section 2: Transportation (IEC 60721-3-2: 1997); German version EN 60721-3-2: 1997
ISO 13485:2003 - Medical devices -- Quality management systems -- Requirements for regulatory purposes
ISO 10993-5 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity

10 CONCLUSION

Based on a comparison of indications, composition, principle of operation, features and technical data, the Sirona CEREC SpeedGlaze is substantially equivalent to the predicate device.